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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,907	03/09/2000	Stale Petter Lyngstadaas	49121	2801

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EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/18/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.



APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

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DATE MAILED:

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on 2/12/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 28-59 is/are pending in the application
- Of the above, claim(s) 36-40, 56-59 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 28, 41-55 is/are rejected.
- ☒ Claim(s) 28-35 is/are objected to.
- ☒ Claim(s) 28-59 are subject to restriction or election requirement

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

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The claims pending are 28-59.

Claims 36-40 and 59 remain withdrawn. The last two sentences in the abstract of Hammarstrom et al. (J. Clin. Periodontology, 24, 669-677, 1997) are taken as a teaching that a species election requirement among the recited species of excipients is proper.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of 2/12/02 (Paper 10) has overcome the perviously stated basis of rejection under 112, second paragraph.

The previously stated 103 rejections over Hammarstrom et al. in view of Haimes et al. (Pat. 6,022,862) and over Carlson-Mann et al. in view of Pat. '862 have been withdrawn. The secondary reference is irrelevant to the claimed invention.

Note newly stated 112 and 102 rejections herein below.

Claims 41-42 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 41 and 42 "The active matrix enamel substance" lacks antecedent basis.

Claim 42 has an improper Markush group by setting of the last three, instead of only the last member, with "and".

In claim 55 "the pharmaceutically or cosmetically acceptable excipient" lacks antecedent basis".

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28, 41-43, 46-47 and 50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammarstrom et al. (EPO 0,263,086, ref. BA).

Hammarstrom et al., ('086) teach use of a preparation of an enamel matrix composition which is the same as that instantly taught. They teach that this composition can be applied to the roots of a tooth to be transplanted, and the thus treated tooth can be implanted. See col. 4. The composition applied to the tooth can thus reasonably be considered as "administred" to the patient when the tooth is implanted.

Claim 28 is so broad as to what is transplanted or grafted, as well as to how, where and when the enamel substance is administered, that the claim is anticipated by the treatment taught by Hammarstrom et al. Further, the claim does not postively even require that transplantation be done; thus mere application of the preparation, as taught by Hammarstom et al in Examples 3-7, properly anticipate.

Dependent claims 41-43 and 46-47 are included because applicant's disclosure shows that an enamel matrix preparation inherently contains a mixture of the recited proteins, that have different molecular weights up to about 120,000.

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Claims 50-51 are considered properly anticipated since applicant's disclosure admits that an enamel matrix preparation would inherently have the property of forming aggregates of the recited size in situ (i.e. at physiological temperature and pH which would be achieved when the coated tooth is implanted).

Claims 52-53 are included since the recited percentages ranges would be inherent to the preparation.

Claim 54 is rejected, since Hammarstrom et al. teach excipients (carriers, diluents) at col.

3.

Claims 28, 41-48, 50-51 and 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammarstrom et al. (EP 0,337,967, ref. BB).

Hammarstrom et al. ('967) disclose essentially the same subject matter with respect to transplantation of a tooth as Hammarstrom et al. ('086); and the claims are considered anticipated, following the same rationale stated supra.

Hammarstrom et al. ('967) show that the enamel matrix preparation of Hammarstrom et al. ('086) can be separated into fractions of proteins of various molecular weight ranges. They show that the fraction having a molecular weight range of about 5,000 to 25,000 containing the androgenins is the active fraction. Hence claims 41-48 are anticipated. See para. Spanning pages 2-3.

Claims 50-51 are rejected for reasons stated with respect to Hammarstrom et al. ('086).

Claims 52-53 are included (see protein content taught in Example 4).

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Claims 54-55 are included because Hammarstrom et al. teach excipients (diluent/carriers), including propyleneglycol alginate (page 3).

Claims 28, 41-42, 46-51 and 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Mellonig (Int. J. Periodontics Restorative Dent. 19, 9-19, 1999, ref. CA).

Mellonig shows a method similar to that of each of the above cited Hammarstrom et al. references. From the disclosure at page 13, paragraph spanning cols. 1 and 2 and first full paragraph of col. 2, it is clear that an excess of the enamel matrix protein derivative preparation (EMD) is applied to the area of surgery. Thus EMD is "administered" to the patient, as required by claim 28. Applicant's discussion of this reference at specification page 4, deems this reference as not anticipating because the "allograft is composed of dead tissue". Since claim 28 does not positively recite that any tissue is grafted/transplanted in the claimed method, the claim is properly anticipated. Further, no claim requires that the grafted material be living, as opposed to dead, tissue.

Dependent claims 41-42 and 46-49 are included because the teachings of Mellonig (page 10, col. 2) and of applicant (page 23) show that EMD inherently has the recited composition of proteins with the recited molecular weights. Claims 51-52 are inherently anticipated, as argued regarding Hammarstrom et al. Claims 54-55 are anticipated by Mellonig at page 12, col. 1, first full paragraph.

Claims 52-53 are included, since the recited percentage ranges would be inherent (e.g. see Hammarstrom et al. '967).

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Claims 29-35 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

June 13, 2002

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/644